Roger Williams University Human Subjects Review Board

Policy on Noncompliance

(8/2021 amendment to the RWU HSRB Policy 2019)

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their research staff, the participants who enroll in research, Human Subjects Review Board (HSRB) members, and designated HSRB staff. All members of any research team conducting human subjects research are required to comply with the provisions and protocols of the HSRB-approved study as well as all related federal regulations, Roger Williams University (University) policies, and state and local laws.

The primary responsibility of the HSRB is to ensure protection of the rights and welfare of research participants. In performing that responsibility, the HSRB addresses allegations of noncompliance with HSRB requirements, University policies, and/or applicable legal regulations governing the conduct of human research, including those outlined by the Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP), the HSRB's Federal Wide Assurance (FWA), and the U.S. Food and Drug Administration.

The HSRB is authorized by the Univeristy and by federal regulations through the Office of Human Research Protections (OHRP) to review allegations of researcher noncompliance, misconduct, and possible resultant harm. In the event of an investigation, the HSRB works collaboratively with the designated Institutional Official (IO) to ensure the applicable policies are being followed. The IO is the authorized signatory on the Federal Wide Assurance (FWA) filed with OHRP to ensure compliance with human subject regulations.

DEFINITIONS

Harm

According to the OHRP, risk of harm as a result of participating in a study includes "physical, psychological, economic, or social harm." As part of the standard HSRB review protocol, researchers disclose any foreseeable risks upon proposal submission, and the HSRB evaluates whether anticipated risks are reasonable in light of the potential benefits of the study. Failure to disclose foreseeable risks or constitutes noncompliance with HSRB protocols and will be fully investigated (see *Procedures)*.

In cases in which study participants, researchers, or others report or experience unforeseen harm, the researcher must also report the incident to the HSRB for further investigation.

Noncompliance

The term "noncompliance" means the failure to comply with accepted standards and regulations set forward by institutional, local, state, and federal policies, as well as the RWU HSRB policies.

Noncompliance with HSRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare. Noncompliance in which a researcher fails to adhere to the laws, regulations, or policies governing human research in such a way that causes substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others is a serious offense requiring investigation and, in some cases, action by the HSRB, and potentially, other departments and programs at RWU (see *Actions/Outcomes*).

Examples of noncompliance include, but are not limited to the following (see also the OHRP Determinations of Noncompliance):

- Failure to obtain HSRB review and approval prior to conducting human subjects research
- Failure to obtain HSRB review prior to HHS grant applications
- Continuation of research activities (i.e. enrolling new participants, collecting data) after a study's approval period has expired
- Inadequate details regarding participant recruitment and selection for participation
- Enrollment procedures did not minimize possible coercion or undue influence
- Failure to obtain, document and maintain appropriate records of informed consent of research subjects
- Inadequate documentation regarding risks to participants and how they will be minimized
- Unreported adaptations to research procedures as outlined in the protocol that was reviewed/approved by the HSRB
- Failure to conduct continuing review at least once per year
- Failure to report unintentional adverse events to the HSRB

PROCEDURES

Reporting Allegations of Noncompliance

Allegations of noncompliance may be submitted by anyone: University employees, students, external researchers or affiliates, and the general public.

A person who wishes to report an allegation of noncompliance should notify the HSRB as soon as is reasonable once the issue comes to their attention as a potential concern by filing the RWU HSRB Incident Report Form. Required information includes the date and time of the allegation, description of the allegation (including the time and date of any observations that raise concerns), and an explanation of the concerns that constitute the allegation.

Allegations should be submitted to the HSRB Administrator or Institutional Official, verbally or in writing. The Roger Williams University Whistleblower Policy protects individuals who report issues in good faith from retalitation for making such a report. The HSRB will maintain confidentiality regarding the identity of the person submitting the allegation to the extent possible.

Initial Evaluation and Action

All allegations of noncompliance are forwarded to the HSRB Administrator and the Institutional Official (IO). If the HSRB Administrator has an actual or perceived conflict of interest, the Institutional Official (IO) will delegate the evaluation and subsequent investigation to an HSRB member who does not have an actual or perceived conflict of interest.

The HSRB Administrator (or designee) evaluates the allegation and the documentation to classify the allegation as follows:

- No action or investigation required
- Requires investigation
- Requires investigation and immediate action

If an investigation is required, the person against whom the allegation is being made is notified. The HSRB Administrator (or designee) may request additional information to document the facts surrounding the allegation. If the person does not respond in a timely manner or does not acknowledge the HSRB concerns, the Administrator (or designee) may contact the person's supervisors about the allegation and request their assistance to resolve the matter.

Individuals notified of allegations and are under investigation may also submit a written rebuttal to the allegation to the HSRB Administrator and/or Institutional Official (IO). Contact information for the HSRB Administrator and the IO is available on the Policies and Membership page of the RWU HSRB website.

Process for Immediate Action

After reviewing the initial allegations and concerns, the HSRB Administrator and Institutional Official (IO) may determine immediate action is necessary due to the seriousness and/or the frequency of violations and/or clear disregard for federal regulations or institutional policies and procedures applicable to human subject research. Examples of immediate action include termination and/or suspension of any or all research activities for one or all of the researchers affiliated with the study.

According to HHS regulations (45 CFR 46.103(a) and (b)(5), the IO may need to report the incident to the OHRP, and if applicable, the FDA. For concerns involving potential legal or ethical violations or breaches of academic integrity, other university officials or individuals affiliated with the research study may also be contacted.

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Process for Investigation

1. The HSRB Administrator convenes a meeting of the HSRB to discuss the allegation and the investigation process, and may designate a subcommittee of the HSRB to assist with the investigation.
2. The investigation proceeds through the collection of information relevant to the allegation. This includes, but is not limited to, interviews with persons affiliated with the allegation, interviewing

research participants and affiliated organizations, and reviewing consent records, data records, and other documents.

3. The HSRB Administrator and/or subcommittee prepares a draft of a summary report of the results of the investigation, to be submitted to the HSRB. The report includes the allegations and concerns and other relevant and pertinent information, documentation, and correspondences. The report may or may not include recommendations for corrective action.
4. The HSRB reviews the material presented by the review team at a convened meeting with quorum of the full board membership. The HSRB votes to determine if the allegation of noncompliance is substantiated and what, if any, corrective actions will be required.

Examples of Corrective Actions include but are not limited to:

- Formal educational interventions
- Minor or major changes in the research procedures and/or consent documents
- Modification of the HSRB continuing review timeline
- Monitoring of research protocols
- Revisions to the informed consent process
- Suspend or terminate HSRB approval/disapprove continuation of the study
- Further investigation/review of other active research protocols
- Disqualifying the investigator from research involving human subjects at the university
- Destruction of data previous collected
- Contacting participants regarding potential for harm
- Contacting editors or grantees regarding previously published data
- Contacting community partners or public organizations and agencies

Outcomes and Final Reporting

The HSRB Administrator and/or subcommittee revise the summary report to reflect any changes in recommendations regarding corrective action as a result of the review meeting.

The HSRB Administrator or a designee communicate the HSRB decision and recommendations to the individual under investigation and the Primary Investigator of the research (if such parties are different). Both parties may submit a response to the HSRB of any concerns regarding the investigation and corrective actions within 30 days of being notified of the decision.